11th Annual General Meeting and Conference of DCVMN

Hyderabad, India
September 15-16

Matching Public Health Needs and Market Opportunities: Factors Influencing Vaccine Capacity Building

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International Vaccine Technology Workshop

1. Provide national policy-makers and scientific subject matter experts with the tools to survey and evaluate a range of technologies used to develop and manufacture biopharmaceutical products that will effectively eliminate health threats
2. Empower decision-makers with the knowledge to determine what technologies are best suited to meet the needs of their nation
3. Identify essential needs and current gaps in vaccine development and manufacturing capacity that must be addressed in order to meet the needs of developing countries
4. Identify drivers and obstacles to the initiation of sustainable vaccine production capacity, as well as recommendations to overcome these challenges
5. Provide an opportunity to foster partnerships between low, mid, and high income nations as well as public and private sector policy makers, technology experts and innovators
6. Discuss roles of stakeholders including government agencies and ministries, international organizations, the private sector, and NGOs
7. Delineate policy options for short-, medium-, and long-term

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Vaccines for Disease Control, Elimination, and Eradication

- Prevent over 2 million deaths every year
- Comparable to providing safe drinking water in reducing mortality rates
- Vaccines have eradicated small pox, Polio in many parts of the world (and large part of India)
- Vaccines are widely acknowledged as one of the most successful and cost – effective public health interventions.

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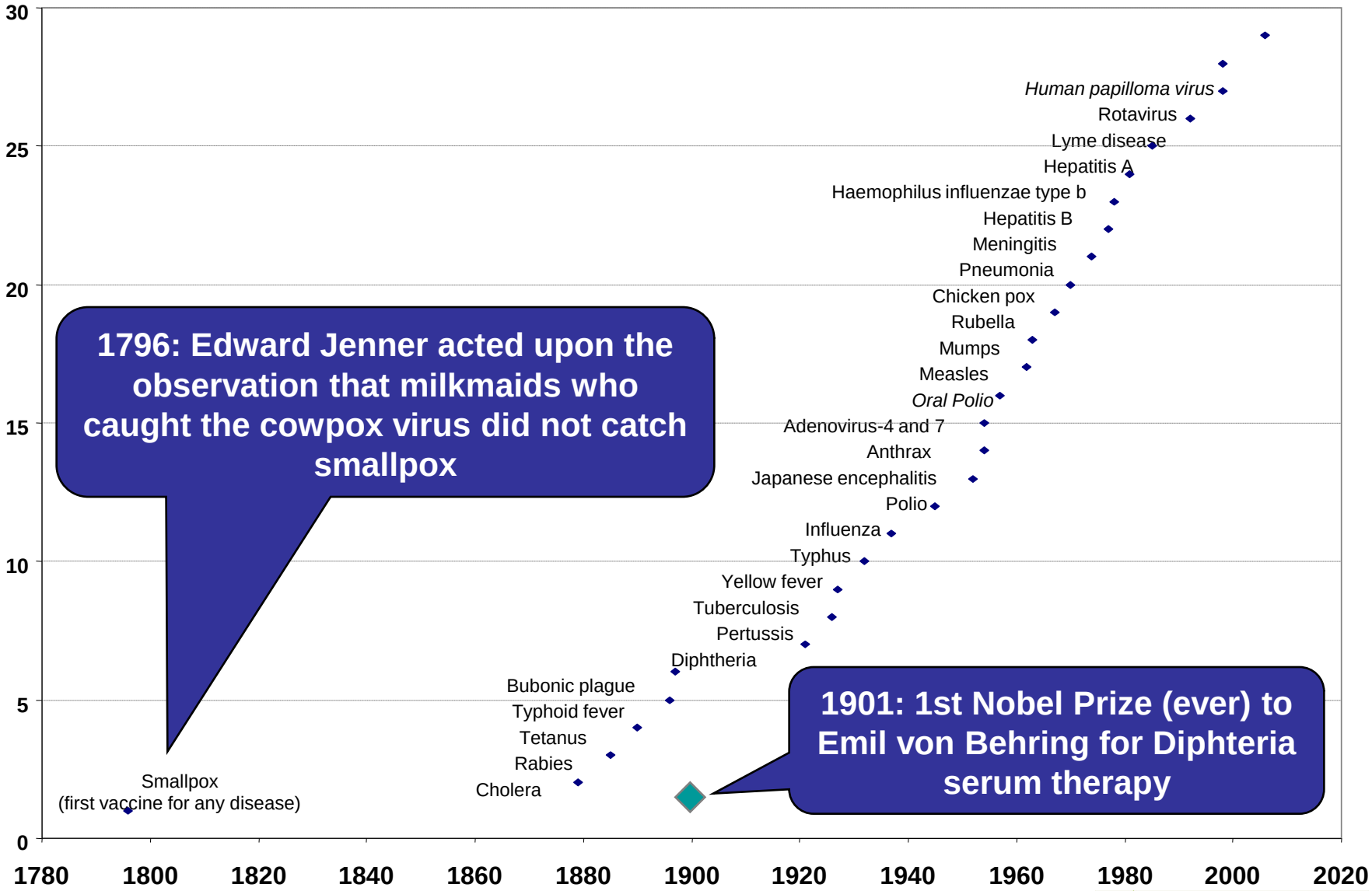
Many Effective Vaccines Available



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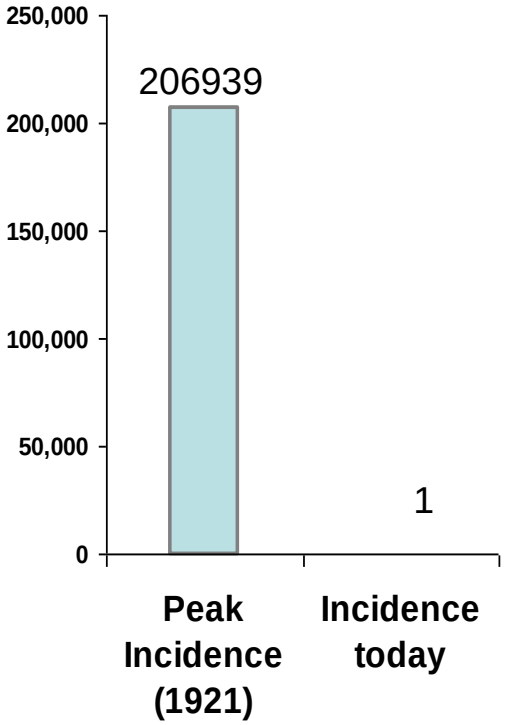
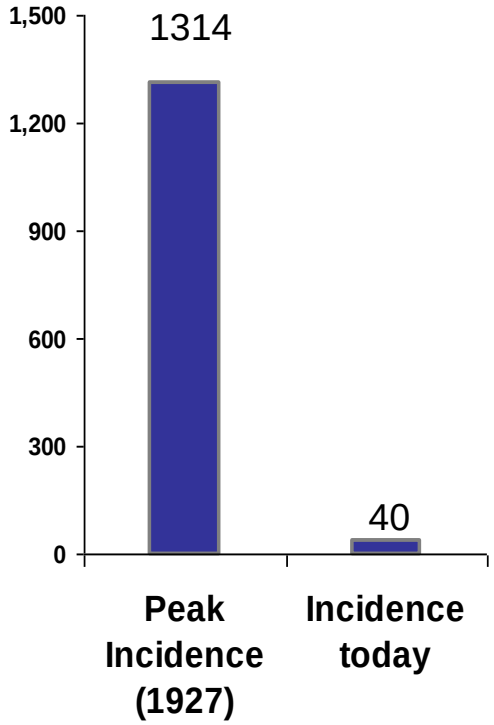
Vaccines Offer Health and Economic Benefits

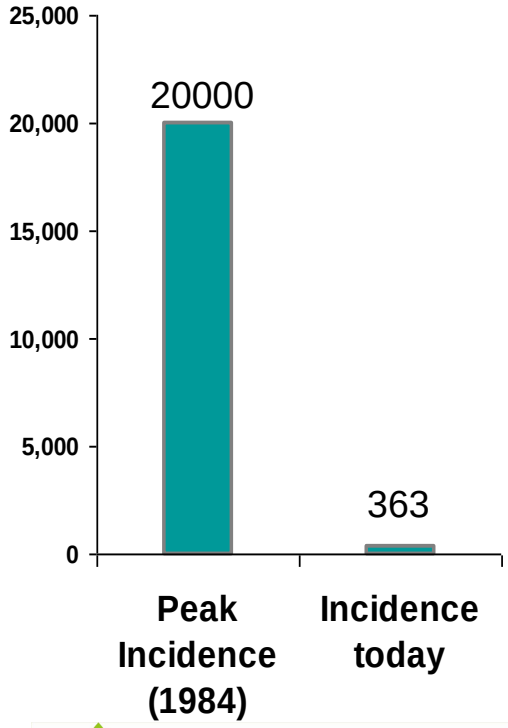
Diphtheria incidence in the US
Mortality 5/10,000 cases



Tetanus incidence in the US
Mortality 3/10 cases



***H. Influenza* type B incidence in the US**
Mortality 2-3/100 cases



Source: Ehreth Vaccine 21:4105-4117 (2003)

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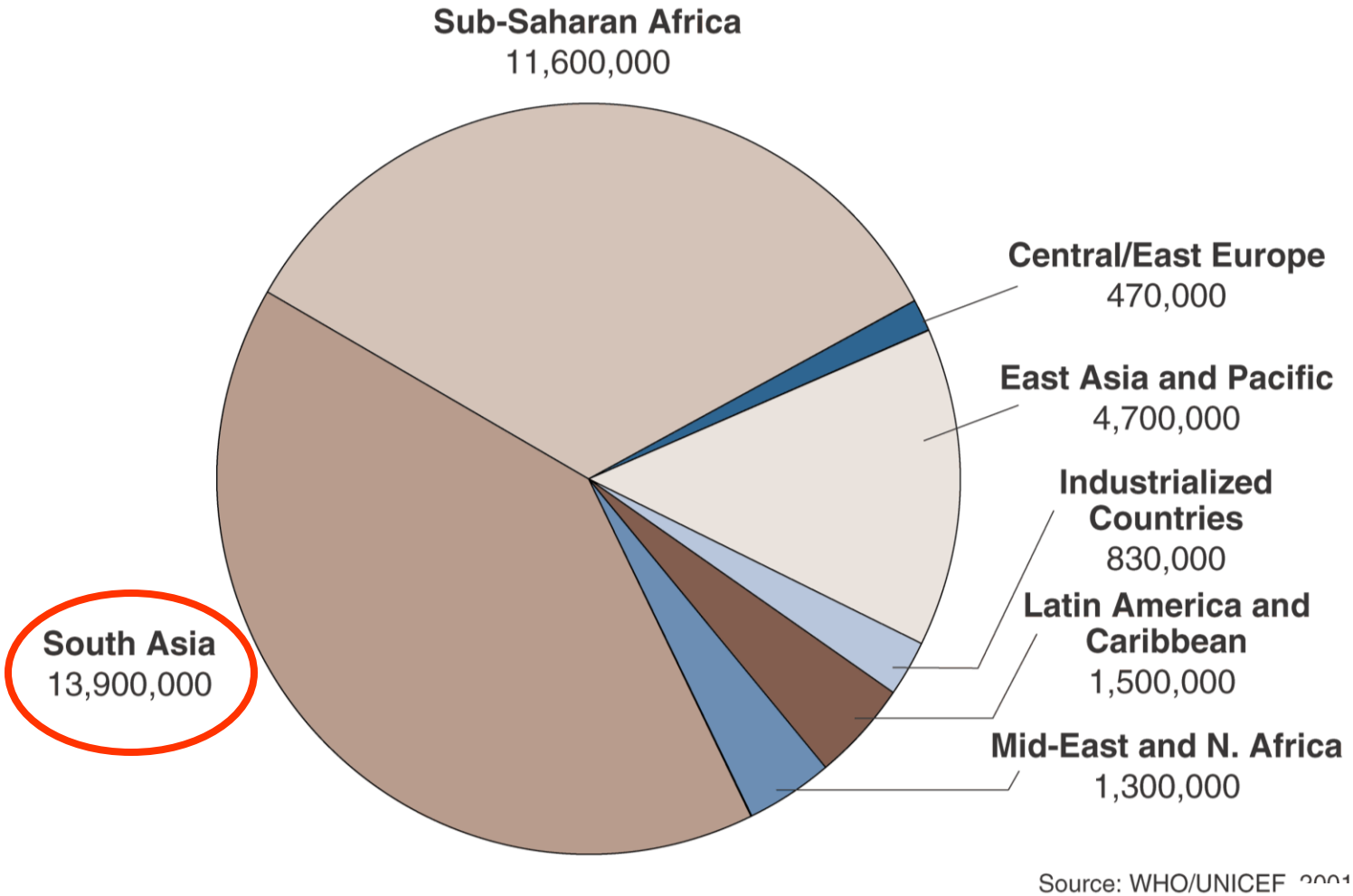
Childhood Immunization: Challenges ahead …



Source: WHO/UNICEF 2001

34 million children are not fully immunized!

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Vaccines have stabilized society, but….

Global vaccine needs are unmet

- Cost, financing, and systems

DW and emerging market needs are unique

- Delivery, cold chain, and transportation
- Disease burden and epidemiologic features
- Role of NRA and WHO

DCVMN have important role

- Indigenous programs
- Partnerships

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Optimizing Vaccine Use

A. Driver (pull)

1. KAP
2. Disease burden
3. Technical expertise at the policy levels
4. Political buy-in
5. Funding for vaccine programs
6. Effective NTAGI
7. Inputs of global frameworks

B. Driver (push)

1. Effective regulatory environment
2. Availability of affordable vaccines
3. National institutions of excellence
4. Public awareness
5. National policy framework, commerce, and trade
6. Funding (national and international)

Affordability

Profitability

Availability

Accessibility

Desirability

Accountability

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Vaccine Finance Sources and Procurement Strategy (WHO-SEARO 2002 Report)

Country (GNP/Capita)	Financing Sources	Procurement (UN)	Local Production
Bangladesh ($350)	Domestic + external	All EPI	Limited
Bhutan ($430)	External	All EPI	
India ($430)	Domestic + external	OPV	Yes*
Indonesia ($1110)	Domestic + external	Measles	Yes
Nepal ($210)	Domestic + external	BCG and OPV	
Sri-Lanka ($810)	Domestic + external	All EPI	
Thailand ($2740)	Domestic		Yes

*Best in this region and developing faster

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National Committees on Vaccination and Immunization

A. The United Kingdom

1. Originally advisory board for polio immunization that became JCVI (1963)
2. Statutory (order 1981, SI1981/597, and NHS Act 2006)
3. Statutory functions of the JCVI extend to England and Wales

B. The United States of America

1. Advisory Committee on Immunization Practices (ACIP) since 1964
2. NITAG is the advisory committee on ACIP
3. Section 311 and 317 of the PHS Act
4. Public Law 92-463.
5. Statutory role (Section 13631 of OBRA of 1993, Public Law 103-66)

C. Sri Lanka

1. Advisory Committee on Communicable Diseases established (mid 1960s)
2. The Quarantine and prevention of Diseases Ordinance of 1897 is the legal basis of ACCD

D. South Korea

1. Korea Advisory Committee on Immunization Practices established by law in 1992

E. India

1. NTAGI established in 2001 by DFW order

State of Vaccination and Immunization (Vaccine 285, 2010)

Country	Policy	Frequency of Meeting	Composition	Host	Vaccine Coverage
U.S.A	Public Law	Once a year*	Academic with USG *(Ex officio)*	CDC	Very good
UK	Public Law	3 times a year	Academic	DH	Very good
Korea	Public Law	4 times a year	Academic and govt.	KCDC	Very good
China	MOH	Once a year	Govt .and academic	CCDC	Very good
Iran	Public Law	4 times a year	Govt. and academia	CDCD	Very good
Sri Lanka	Public Law	4 times a year	Govt. and academia	DGHS	Very good
India	DHFW	6 times over 9 years	Govt . and academia	DFW	Uneven Coverage

Total Health Expenditure in India (2001-2002)*

Expenditure	Exp. in Rs 000s	Percapita Exp (in Rs)	% Distribution	% of GDP
Public	214,391,018	207	20.3	0.94
Private	818,104,032	790	77.4	3.58
External	24,846,646	24	2.3	0.11
Total	1,057,341,696	1021	100	4.63

*Report of National Health Accounts, India 2001-2002

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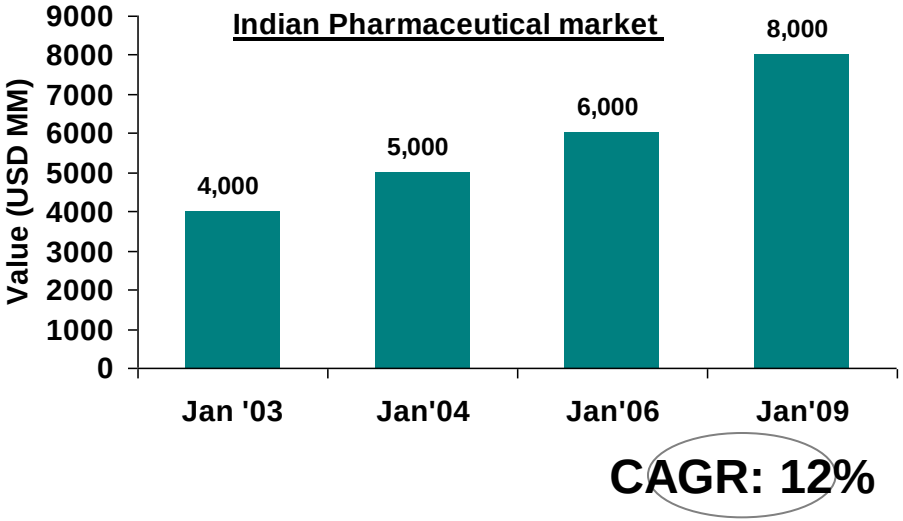
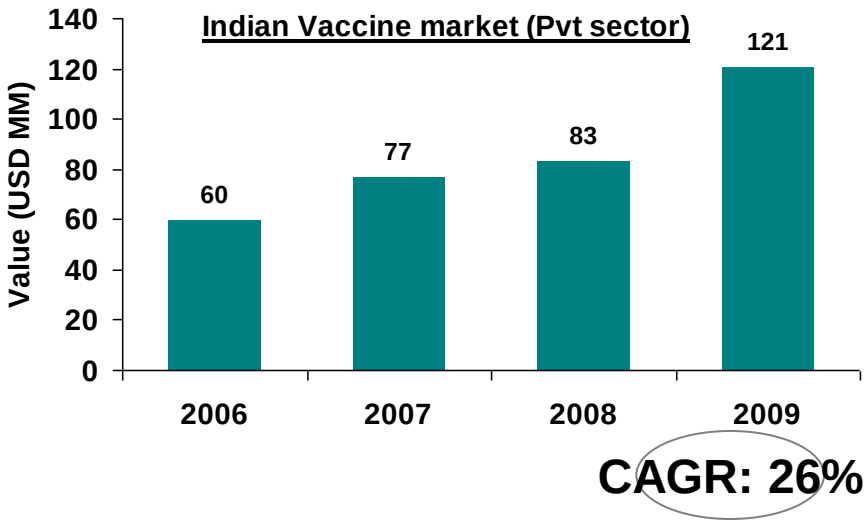
Level of Health Spending in Selected Countries, 2002*

Country	Total as a % of GDP	Public exp as a % of total
USA	14.6	44.9
UK	7.7	83.4
Brazil	7.9	45.9
China	5.8	33.7
Sri Lanka	3.7	48.7
Indonesia	3.2	36.0
India	4.6	20.3

Report of National Health Accounts, India,2001- 2002

Vaccines Market Growing Twice as Fast as Indian Pharma Market





- **Vaccines market growth continues to outpace pharmaceuticals growth**
- **New introductions (PREVNAR, GARDASIL, CERVARIX, ROTARIX) and epidemic (Flu) vaccines are leading the charge**
- **Indian vaccine market estimated at $ 665M in ’07-08 and growth of 20%** (source: Datamonitor)

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Regulatory Scenario conducive to Vaccine development

- Vaccines enjoy higher agenda status in WHO India efforts
- Indian MOH and other agency and Govt laboratories give high priority to vaccine development and usage
- HHS/FDA collaboration with Indian NRA
- Consequently national regulatory authorities provide higher priority to vaccines that answer medical need in India

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Challenges Specific to Vaccines

- Additional Regulatory committees under GEAC (RCGM/IBSC) review and approve vaccines made with GMO
  - Time and procedures for review
  - Committee posts meeting minutes on their website. For an investigational vaccine likely to have significant competition, this is a major consideration

- Testing of the vaccine by the Government Laboratory before release of investigational and market batch.
  - Timing of release
  - Transfer of assays to government laboratory at investigational stage

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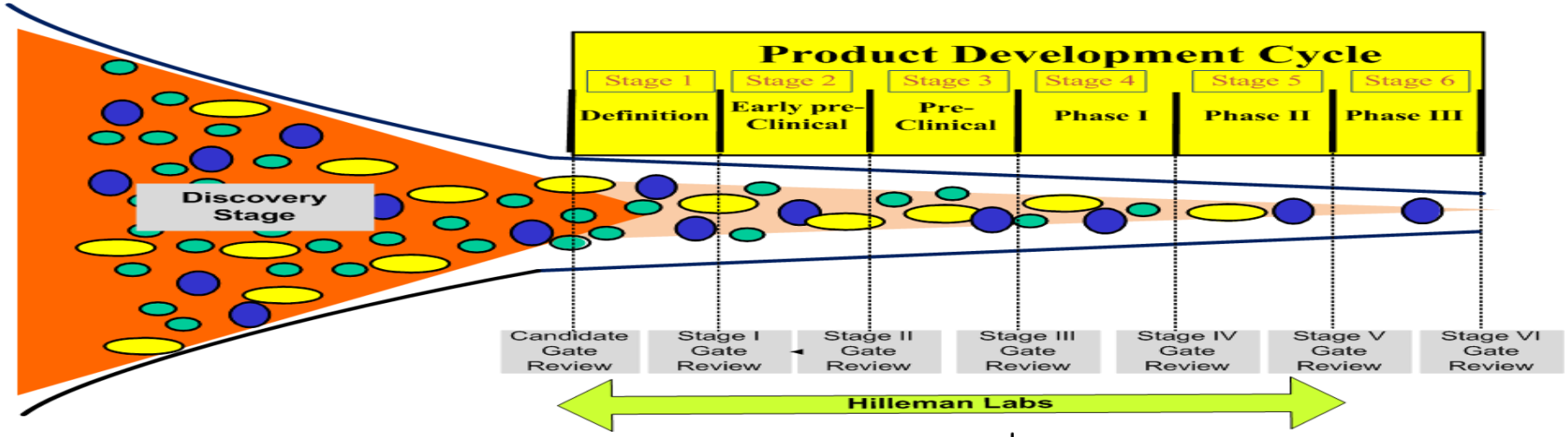
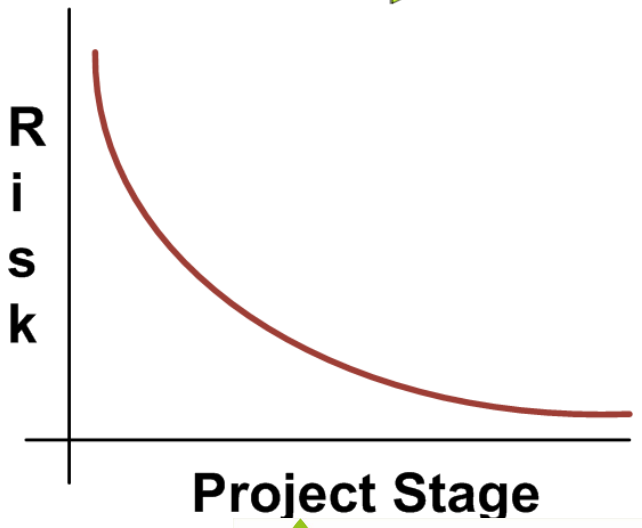
Risk Mitigation – Manufacturing Discipline and Interface with NRA



- **Structured stage gate review process with Go/NoGo/Redirect decisions. Alignment with all functional areas (R&D/ Process Development/ Validation/ Analytical/ Clinical/ Quality systems/Regulatory/ Supply chain)**
- **Formal periodic meeting with NRA through product life cycle**
- **NRA alignment on key decision points**
- **Eliminate surprises for developer**



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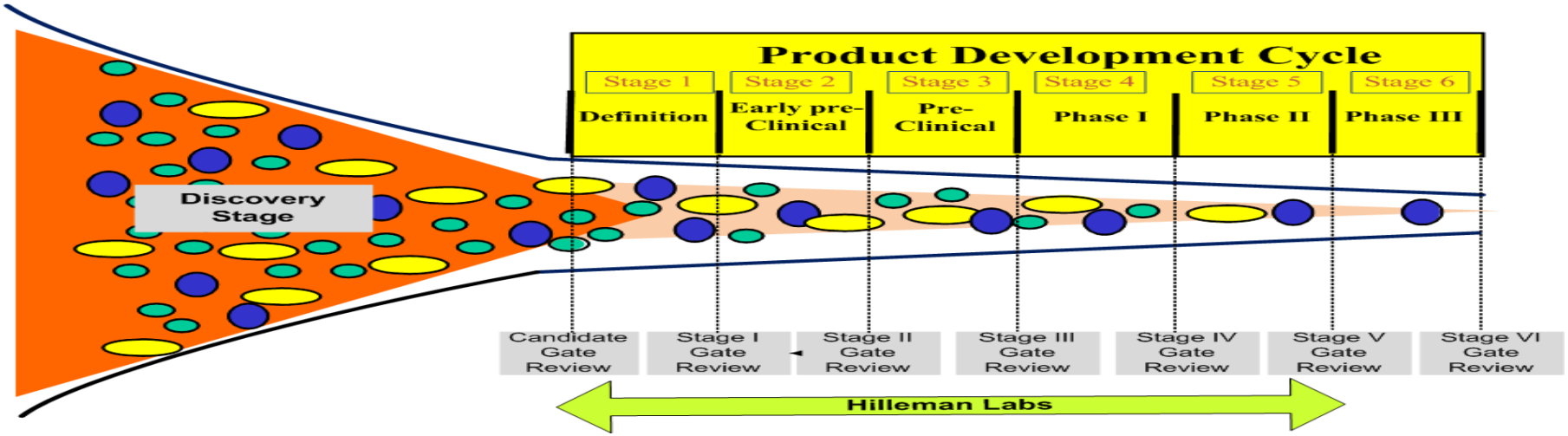
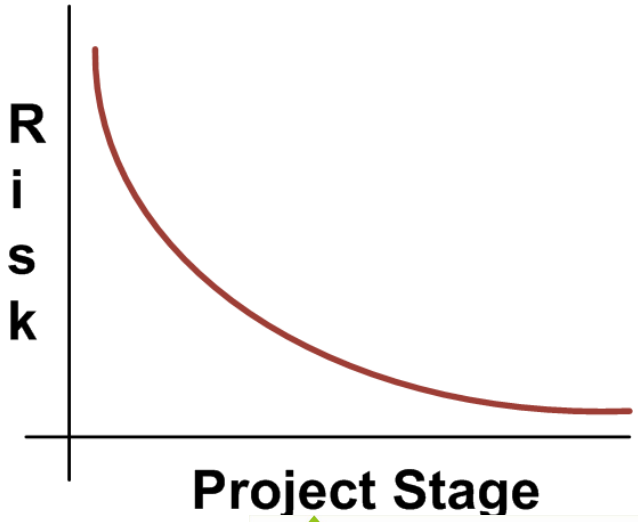
Risk Mitigation – Testing and Release of the Product



- **WHO Guidelines and TRS (Tech Report Series) with quantitative instead of qualitative recommendations.**
  - **% impurities at various process stages**
  - **Stability indicating parameters and their ranges**



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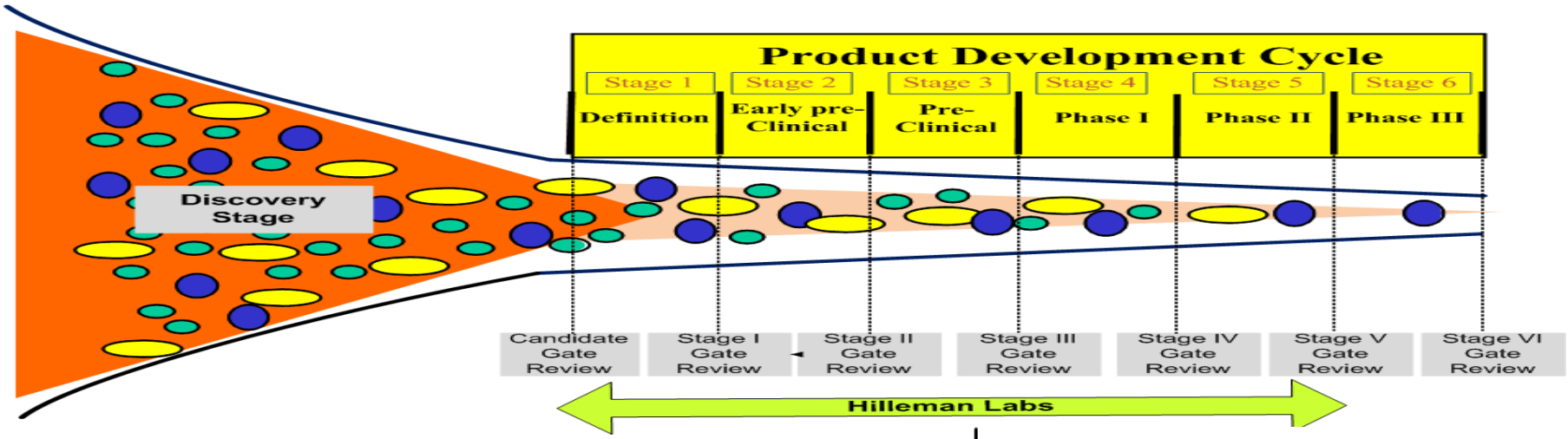
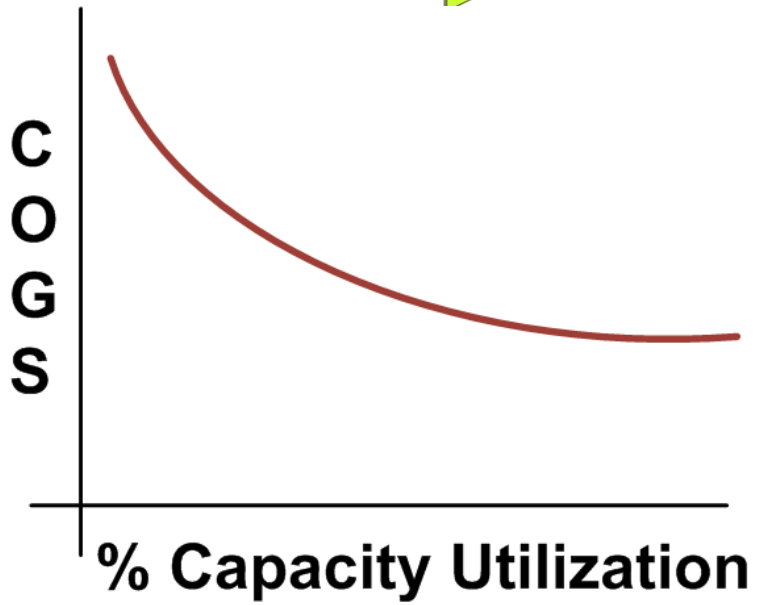
Risk Mitigation – Capacity of Production Using Target Volume Expectation



- **Forward-looking volume commitments will allow adequate capacity utilization**
- **Scientific risk-based approach for change management**



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Summary: Need for Safe, Effective, and Affordable Vaccines

- Need for pediatrics and adult population
  - Competition will bring cost down
  - DVMNC have important role to play (e.g. Hep B)
- Optimize existing vaccines
  - Thermostable formulation
  - Alternative delivery systems, antigen-sparing (rabies vaccine)
  - Use of new, human-useable adjuvants
- Development of novel vaccines
  - New expression systems
  - Novel vaccines by DCVMN (Hep E, Chickungunya, etc)
  - Tech transfer by MNCs (Sanofi, Merck)
- Policy and regulatory environment
  - Sample and strain sharing between entities and countries
  - Harmonization of regulations
  - Support from WHO, PATH for DCVMN
  - NRA in DW and EM to develop effective & transparent regulatory environment
  - Emerging (high GDP economies) to place appropriate priority for introducing new vaccines in national programs

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Thank you for your attention

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